

5

ABSTRACT

A unit dosage form, such as a capsule or the like, for delivering drugs into the body in a circadian release fashion comprising one or more populations of drug-containing particles (beads, pellets, granules, etc.) is disclosed. Each bead population exhibits a pre-designed rapid or sustained release profile with or without a predetermined lag time of 3 to 5 hours. Such a circadian rhythm release drug delivery system is designed to provide a plasma concentration – time profile, which varies according to physiological need at different times during the dosing period, i.e., mimicking the circadian rhythm and severity/manifestation of gastric acid secretion (and/or midnight gerd), predicted based on pharmaco-kinetic and pharmaco-dynamic considerations and *in vitro/in vivo* correlations.

314155